

**REMARKS**

Claims 21-43 are pending. Claims 21-25, 28 and 31 were rejected under §102(e). Claims 26, 27, 29, 30 and 32- 39 were rejected under 35 U.S.C. 103(a). New claims 40-43 have been added.

**November 10, 2003 Telephone Interview**

During a telephone interview conducted on November 10, 2003, the Examiner and Applicant's representative discussed Brown U.S. Patent No. 6,161,095, the primary asserted reference. Applicant reminded the Examiner of the previous April 20, 2003 interview in this case where agreement in principle had been made regarding the conceptual difference between Brown and the present invention. At that time, the Examiner held that the claims could have still been read broadly to encompass the teachings of Brown. During the current interview, the Examiner continued to agree that there was a conceptual difference between Brown and the present invention. Specifically, Brown does not teach a system or method for a patient to record medical treatments, or events, that were not previously programmed into the patient device. As discussed below, Applicant respectfully submits that the claims as amended clearly articulate this distinction.

**Claim Rejections 35 U.S.C. §102**

Claims 21-25, 28 and 31 were rejected as anticipated under 35 U.S.C. §102(e) by Brown (U.S. Patent No. 6,161,095). Applicant has amended the presented claims to clarify the distinguishing characteristics between the present invention and Brown and thereby overcome the Examiner's rejections.

Applicant believes that the amended claims clearly articulate the distinction between the present invention and compliance monitoring systems, such as those disclosed in Brown. For example, as amended claims 21-25, 28 and 31 require “a record indicating a patient initiated decision to self administer a medical treatment.” Applicant, respectfully submits that the new claim language, requiring that the record indicate a “patient initiated decision” to self administer a medical treatment, fully distinguishes these claims from Brown. In Brown an alarm sounds, indicating a pre-programmed instruction to conduct the required treatment. Thus, the patient’s following the instructions defined in the pre-determined treatment. In contrast, claims 21-25, 28 and 31 require the recordation of a medical treatment for which the decision to perform the treatment was initiated by the patient and is not in response to a pre-programmed alarm, schedule or regime. Applicant believes that this claim language articulates the distinction over Brown.

#### **Claim Rejections 35 U.S.C. §103**

The Examiner has rejected claims 26, 27, 29, 30 and 32- 39 as obvious under 35 U.S.C. §103(a) over Brown (U.S. Patent No. 6,161,095) in view of various other references. Applicant has amended the presented claims to clarify the distinguishing characteristics between the present invention and Brown and thereby overcome the Examiner’s rejections.

For the same reasons discussed above with respect to anticipation, Applicant believes that the amended claims clearly articulate the distinction between the present invention and compliance monitoring systems, such as those disclosed in Brown. Claims 26, 27 29 and 30 recite the same “patient initiated decision” limitation discussed above. Similarly, claims 32-35 recite a record that “indicates a patient initiated decision to self administer a medical treatment;” and claims 36-39 require a “medical treatment record indicating a-patient initiated decision to

self administer a medical treatment.” Just as discussed above, Brown does not teach the recordation of a medical treatment for which the decision to perform the treatment was initiated by the patient and is not in response to a pre-programmed alarm, schedule, or regime. These claims, therefore, each require a limitation that is not present in Brown. Thus, Applicant respectfully submits that the Examiner’s obviousness rejections with respect to these claims should be withdrawn.

Applicant will not address the Examiner’s representations with respect to the other cited prior art because Brown formed the basis for all of the pending rejections. Distinguishing over Brown, therefore, addresses all of the pending rejections.

#### **New Claims**

Applicant has added new claims 40-43. Applicant submits that no new matter has been added and that support for these claims can be found throughout the specification. See e.g. page 14. Each of these claims requires the recordation of a medical treatment administered in response to an unforeseen event. The pre-programmed device of Brown clearly does not teach this limitation. Applicant, therefore, believes these claim to be patentable.

#### **CONCLUSION**

Based on the foregoing amendments and remarks, Applicants respectfully request reconsideration and withdrawal of the rejection of claims and allowance of this application.

#### **AUTHORIZATION**

The Commissioner is hereby authorized to charge any additional fees, which may be required for consideration of this Amendment to Deposit Account No. 13-4500, Order No. 4297-4017. A DUPLICATE OF THIS DOCUMENT IS ATTACHED.

In the event that an extension of time is required, or which may be required in addition to that requested in a petition for an extension of time, the Commissioner is requested to grant a petition for that extension of time which is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to Deposit Account No. 13-4500, Order No. 4297-4017. A DUPLICATE OF THIS DOCUMENT IS ATTACHED.

Respectfully submitted,  
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